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1632-11
915
#3
Atty. Dkt. No. SALK2270.US5
(088802-5212)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Evans et al.

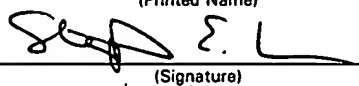
Title: NOVEL STEROID-ACTIVATED
NUCLEAR RECEPTORS AND USES
THEREFOR

Appl. No.: 10/081,555

Filing Date: 02/20/2002

Examiner:

Art Unit: 1632

CERTIFICATE OF MAILING I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as First Class Mail in an envelope addressed to: Commissioner for Patents, Washington, D.C. 20231, on the date below. <u>Stephen E. Reiter, Reg. 31,192</u> (Printed Name)  (Signature) <u>8/19/02</u> (Date of Deposit)
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TRANSMITTAL SHEET

Commissioner for Patents
Washington, D.C. 20231

Sir:

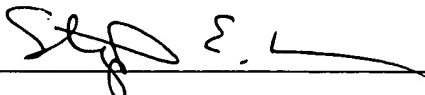
Transmitted herewith for the above-identified application please find:

- Information Disclosure Statement
- Copies of Form PTO-1449 from co-pending applications
- Postcard

No fee is deemed necessary in connection with the filing of this Information Disclosure Statement. However, if any fee is required, authorization is hereby given to charge the amount of any fee to Deposit Account No. 50-0872.

Respectfully submitted,

Date 8/19/02

By 

FOLEY & LARDNER
Customer Number: 30542
30542
30542

Stephen E. Reiter
Attorney for Applicant
Registration No. 31,192

PATENT TRADEMARK OFFICE
Telephone: (858) 847-6711
Facsimile: (858) 792-6773

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AUG 30 2002
TECH CENTER 1600/2900

#8

Atty. Dkt. No. SALK2270.US5
(088802-5212)



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Evans et al.
Title: NOVEL STEROID-ACTIVATED
NUCLEAR RECEPTORS AND USES
THEREFOR
Appl. No.: 10/081,555
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Examiner:
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--

INFORMATION DISCLOSURE STATEMENT
UNDER 37 CFR §1.56

Commissioner for Patents

Washington, D.C. 20231

Sir:

Applicants submit, for consideration by the examiner, references relating to the above-identified application. For the convenience of the examiner, these references are listed on the attached Forms PTO-1449 that were filed in co-pending parent application Serial No. 09/458,366 filed 12/09/1999, of which this application is a divisional, as well as application Serial No. 09/227,718 filed 01/08/1999 and application Serial No. 09/005,286 filed 01/09/1998, of which the parent application is a continuation-in-part. As provided in 37 CFR §1.98(d), copies of the documents listed on the form are not being provided since they were previously submitted to the United States Patent & Trademark Office.

The submission of any document herewith, which is not a statutory bar, is not intended as an admission that such document constitutes prior art against the claims of the present application or that such document is considered material to patentability as defined in 37 CFR §1.56(b). Applicants do not waive any rights to take any action which would be appropriate to antedate or otherwise remove as a competent reference any document which is determined to be a *prima facie* art reference against the claims of the present application.

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Atty. Dkt. No. SALK2270.US5
(088802-5212)

TIMING OF THE DISCLOSURE

The listed documents are being submitted in compliance with 37 CFR §1.97(b), before the mailing date of the first Office Action on the merits.

RELEVANCE OF EACH DOCUMENT

All of the documents are in English.

Applicants respectfully request that any listed document be considered by the Examiner and be made of record in the present application and that an initialed copy of Form PTO-1449 be returned in accordance with MPEP §609.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 CFR §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 50-0872. Should no proper payment be enclosed herewith, as by a check being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 50-0872.

Respectfully submitted,

Date

8/19/02

By

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Attorney for Applicant
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PATENT
Attorney Docket No.: SALK2270

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:
Evans and Blumberg

Serial No.: 09/005,286

Filed: January 9, 1998

For: NOVEL STEROID-ACTIVATED
NUCLEAR RECEPTORS AND
USES THEREFOR

) Group Art Unit: 1643

) Examiner: Unassigned

) CERTIFICATION UNDER 37 CFR § 1.7

) I hereby certify that the documents referred to as
enclosed herein are being deposited with the United
States Postal Service as first class mail on this date,
7/8/98, 1998, in an
envelope addressed to: Assistant Commissioner for
Patents, Washington, D.C. 20231

) Stephen E. Reiter, Reg. No.: 31,192

) (Name of person mailing paper)

) Signature

Date

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AUG 30 2002

TECH CENTER 1600/2900

Assistant Commissioner for Patents
Washington, D.C. 20231

INFORMATION DISCLOSURE STATEMENT

Sir:

In accordance with 37 C.F.R. 1.97, enclosed are references relating to the above-identified application. For the convenience of the Examiner, these references are listed on the attached Form PTO-1449 and a copy of each is enclosed herewith.

It is respectfully requested that these references be considered in the examination of this application and their consideration be made of written record in the application file.

In re Application of:
Evans and Blumberg
Serial No.: 09/005,286
Filed: January 9, 1998
Page 2

PATENT
Attorney Docket No.: SALK2270


No fee is deemed necessary in connection with the filing of this Information Disclosure Statement. However, if any fee is required, authorization is hereby given to charge the amount of any such fee to Deposit Account No. 07-1895.

Respectfully submitted,

7/8/98
Date

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 US Department of Commerce Patent and Trademark Office	ATTY DOCKET NO.: SALK 2270	SERIAL NO.: 09/005,286
	APPLICANT(S): Evans and Blumberg	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT	FILING DATE: Jan. 9, 1998	GROUP ART UNIT: 1643

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U.S. PATENT DOCUMENTS

AUG 30 2002

EXAM. INITIALS	DOCUMENT NUMBER	DATE	NAME	CLASS	SUB- CLASS	DATE
	NONE					

FOREIGN PATENT DOCUMENTS

EXAM. INITIALS	DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB- CLASS	TRANSLATION (YES/NO)
	NONE					


OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages)

	Adlercreutz and Mazur, "Phyto-oestrogens and Western Diseases" <i>Ann. Med.</i> 29:95-120 (1997)
	Altschul, et al., "Basic Local Alignment Search Tool" <i>J. Mol. Biol.</i> 215:403-140 (1990)
	Baes, et al., "A New Orphan Member of the Nuclear Hormone Receptor Superfamily That Interacts with a Subset of Retinoic Acid Response Elements" <i>Molecular and Cellular Biology</i> 14 (3):1544-1552 (1994)
	Bahouth, et al., "Immunological approaches for probing receptor structure and function" <i>TIPS</i> (12):338-343 (1991)
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	Blumberg, et al., "Novel retinoic acid receptor ligands in <i>Xenopus</i> embryos" <i>Proc. Natl. Acad. Sci. USA</i> 93:4873-4878 (1996)

EXAMINER	DATE CONSIDERED
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EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

**COPY OF PAPERS
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FORM 1449  US Department of Commerce Patent and Trademark Office	ATTY DOCKET NO.: SALK 2270	SERIAL NO.: 09/005,286
	APPLICANT(S): Evans and Blumberg	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT	FILING DATE: Jan. 9, 1998 <div style="text-align: center; font-weight: bold; font-size: 1.2em;">RECEIVED</div>	GROUP ART UNIT: 1643

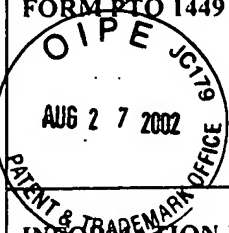
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		Denison and Whitlock, Jr., "Xenobiotic-inducible Transcription of Cytochrome P450 Genes" <i>The Journal of Biological Chemistry</i> 270 (31):18175-18178 (1995)
		Devereaux, et al., "A comprehensive set of sequence analysis programs for the VAX" <i>Nucleic Acids Research</i> 12 (1):387-395 (1984)
		Elshourbagy and Guzelian, "Separation, Purification, and Characterization of a Novel Form of Hepatic Cytochrome P-450 from Rats Treated with Pregnenolone-16 α -carbonitrile" <i>The Journal of Biological Chemistry</i> 255 (4):1279-1285 (1980)
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		Evans, R. M., "The Steroid and Thyroid Hormone Receptor Superfamily" <i>Science</i> 240:889-895 (1988)
		Fernandez-Salguero and Gonzalez, "The CYP2A gene subfamily: species differences, regulation, catalytic activities and role in chemical carcinogenesis" <i>Pharmacogenetics</i> 5:S123-S128 (1995)
		Forman, et al., "Hypolipidemic drugs, polyunsaturated fatty acids, and eicosanoids are ligands for peroxisome proliferator-activated receptors α and δ " <i>Proc. Natl. Acad. Sci. USA</i> 94:4312-4317 (1997)

EXAMINER	DATE CONSIDERED
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FORM PTO 1449 US Department of Commerce Patent and Trademark Office 	ATTY DOCKET NO.: SALK 2270	AUG 30 2002 SERIAL NO.: TECH CENTER 1600/290
	APPLICANT(S): Evans and Blumberg	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT	FILING DATE: Jan. 9, 1998	GROUP ART UNIT: 1643

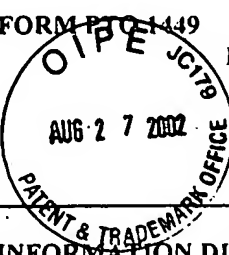
	Forman, et al., "Unique in Response Pathways Are Established by Allosteric Interactions among Nuclear Hormone Receptors" <i>Cell</i> 81:541-550 (1995)
	Gonzalez, et al., "Complete cDNA and Protein Sequence of a Pregnenolone 16 α -Carbonitrile-induced Cytochrome P-450" <i>The Journal of Biological Chemistry</i> 260 (12):7435-7441 (1985)
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	Gottlicher, et al., "Fatty acids activate a chimera of the clofibrilic acid-activated receptor and the glucocorticoid receptor" <i>Proc. Natl. Acad. Sci. USA</i> 89:4653-4657 (1992)
	Hankinson, O., "THE ARYL HYDROCARBON RECEPTOR COMPLEX" <i>Ann. Rev. Pharmacol. Toxicol.</i> 35:307-340 (1995)
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	Hollenberg, et al., "Primary structure and expression of a functional human glucocorticoid receptor cDNA" <i>Nature</i> 318 (6047):635-641 (1985)
	Jonat, et al., "Antitumor Promotion and Antiinflammation: Down-Modulation of AP-1 (Fos/Jun) Activity by Glucocorticoid Hormone" <i>Cell</i> 62:1189-1204 (1990)

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FORM PTO 1449 US Department of Commerce Patent and Trademark Office 	ATTY DOCKET NO.: SALK 2270	SERIAL NO.: TECH CENTER 1600/290C
	APPLICANT(S): Evans and Blumberg	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT	FILING DATE: Jan. 9, 1998	GROUP ART UNIT: 1643


	Juchau, M.R., "SUBSTRATE SPECIFICITIES AND FUNCTIONS OF THE P450 CYTOCHROMES" <i>Life Sciences</i> 47:2385-2394 (1990)
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	Needleman and Wunsch, "A General Method Applicable to the Search for Similarities in the Amino Acid Sequence of Two Proteins" <i>J. Mol. Biol.</i> 48:443-453 (1970)
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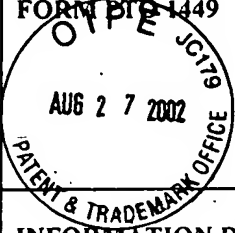
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FORM PTO 1449 US Department of Commerce Patent and Trademark Office 	ATTY DOCKET NO.: SALK 2270	SERIAL NO.: TECH CENTER 1600/2901
	APPLICANT(S): Evans and Blumberg	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT	FILING DATE: Jan. 9, 1998	GROUP ART UNIT: 1643

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	Scheutz and Guzelian, "Induction of Cytochrome P-450 by Glucocorticoids in Rat Liver I. EVIDENCE THAT GLUCOCORTICOIDS REGULATE INDUCTION OF CYTOCHROME p-450 BY A NONCLASSICAL RECEPTOR MECHANISM" <i>The Journal of Biological Chemistry</i> 259 (3):2007-2012 (1984)
	Scheutz, et al., "Induction of Cytochrome P-450 by Glucocorticoids in Rat Liver I. EVIDENCE THAT GLUCOCORTICOIDS AND PREGNENOLONE 16 α -CARBONITRILE REGULATE <i>DE NOVO</i> SYNTHESIS OF A COMMON FORM OF CYTOCHROME P-450 IN CULTURES OF ADULT RAT HEPATOCYTES AND IN THE LIVER <i>IN VIVO</i> " <i>The Journal of Biological Chemistry</i> 259 (3):1999-2006 (1984)
	Schuele, et al., "Functional Antagonism between Oncoprotein c-Jun and the Glucocorticoid Receptor" <i>Cell</i> 62:1217-1226 (1990)
	Selye, H., "Hormones and Resistance" <i>Journal of Pharmaceutical Sciences</i> 60 (1):1-28 (1971)
	Smith, et al., "A novel nuclear receptor superfamily member in <i>Xenopus</i> that associates with RXR, and shares extensive sequence similarity to the mammalian vitamin D3 receptor" <i>Nucleic Acids Research</i> 22 (1):66-71 (1994)
	Staden, R., "The current status and portability of our sequence handling software" <i>Nucleic Acids Research</i> 14 (1):217-231 (1986)
	Sucov, et al., "Characterization of an autoregulated response element in the mouse retinoic acid receptor type β gene" <i>Proc. Natl. Acad. Sci. USA</i> 87:5392-5396 (1990)
	Umesono et al., "Direct Repeats as Selective Response Elements for the Thyroid Hormone, Retinoic Acid, and Vitamin D ₃ Receptors" <i>Cell</i> 65:1255-1266 (1991)

EXAMINER	DATE CONSIDERED
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FORM 1449 US Department of Commerce Patent and Trademark Office 	ATTY DOCKET NO.: SALK 2270	SERIAL NO.: 09/005,286
INFORMATION DISCLOSURE STATEMENT BY APPLICANT	APPLICANT(S): Evans and Blumberg	
	FILING DATE: Jan. 9, 1998	GROUP ART UNIT: 1643

	Willy, et al., "LXR, a nuclear receptor that defines a distinct retinoid response pathway" <i>Genes & Development</i> 9:1033-1045 (1995)
	Yang-Yen, et al., "Transcriptional Interference between c-Jun and the Glucocorticoid Receptor: Mutual Inhibition of DNA Binding Due to Direct Protein-Protein Interaction" <i>Cell</i> 62:1205-1215 (1990)

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Atty. Dkt. No. SALK2270
(088802-5201)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Evans and Blumberg

Title: NOVEL STEROID-ACTIVATED
NUCLEAR RECEPTORS AND
USES THEREFOR

Appl. No.: 09/005,286

Filing Date: January 9, 1998

Examiner: M.K. Zeman

Art Unit: 1631

<p>CERTIFICATE OF MAILING</p> <p>I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as First Class Mail in an envelope addressed to: Commissioner for Patents, Washington, D.C. 20231, on the date below.</p> <p><u>Stephen E. Reiter</u> (Printed Name)</p> <p><u>[Signature]</u> (Signature)</p> <p><u>December 26, 2001</u> (Date of Deposit)</p>

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT
UNDER 37 CFR §1.97(c)

Commissioner for Patents
Washington, D.C. 20231

Sir:

Submitted herewith on Form PTO-1449 is a listing of documents known to Applicants in order to comply with Applicants' duty of disclosure pursuant to 37 CFR §1.56. A copy of each listed document is being submitted to comply with the provisions of 37 CFR §1.97 and §1.98.

The submission of any document herewith, which is not a statutory bar, is not intended as an admission that such document constitutes prior art against the claims of the present application or that such document is considered material to patentability as defined in 37 CFR §1.56(b). Applicants do not waive any rights to take any action which would be appropriate to antedate or otherwise remove as a competent reference any document which is determined to be a *prima facie* art reference against the claims of the present application.

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TECH CENTER 1600/2900



TIMING OF THE DISCLOSURE

The listed documents are being submitted in compliance with 37 CFR §1.97(c), before the mailing date of either a final action under 37 CFR §1.113, a notice of allowance under 37 CFR §1.113, or an action that otherwise closes prosecution in the application.

RELEVANCE OF EACH DOCUMENT

All of the documents are in English.

Applicants respectfully request that any listed document be considered by the Examiner and be made of record in the present application and that an initialed copy of Form PTO-1449 be returned in accordance with MPEP §609.

FEE

A fee in connection with submission of an supplemental information disclosure statement under 37 CFR §1.97(c) in the amount of \$180.00 in accordance with 37 CFR §1.17(p) is attached.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 50-0872. Should no proper payment be enclosed herewith, as by a check being in the wrong amount, unsigned, post-dated, otherwise

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(088802-5201)

improper or informal or even entirely missing, the Commissioner is authorized to charge
the unpaid amount to Deposit Account No. 50-0872.



Respectfully submitted,

Date: December 26, 2001

By

A handwritten signature in black ink, appearing to read "Stephen E. Reiter", written over a horizontal line.

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Stephen E. Reiter
Attorney for Applicant
Registration No. 31,192

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Page 1 of 1

Form PTO-1449 (MODIFIED)	U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE	ATTY. DOCKET NO. SALK2270	SERIAL NO. 09/005,286
INFORMATION DISCLOSURE CITATION <i>(Use several sheets if necessary)</i>		APPLICANT Evans and Blumberg	
		FILING DATE 01/09/1998	GROUP ART UNIT 1631

U.S. PATENT DOCUMENTS

EXAMINER INITIAL	REF	DOCUMENT NUMBER	DATE	NAME	CLASS	SUB- CLASS	FILING DATE IF APPROPRIATE

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AUG 30 2002

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FOREIGN PATENT DOCUMENTS

	REF	DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB- CLASS	TRANSLATION	
							YES	NO
	A1	WO 99/19354	4/22/99	PCT (Berkenstam et al.)				
	A2	WO 99/48915	9/30/99	PCT (Kliewer et al.)				
	A3	WO 99/61622	12/2/99	PCT (Liddle et al.)				

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

EXAMINER	DATE CONSIDERED
-----------------	------------------------

* **EXAMINER:** Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include any copy of this form with next communication to applicant.

FORM PTO-1449 U.S. Department of Commerce Patent and Trademark Office	Docket No. SALK2270-1	Serial No.: 09/227,718
	Applicant(s): Ronald M. Evans	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT	Filing Date: January 8, 1999	Group Art Unit: 1603

AUG 30 2002

U.S. PATENT DOCUMENTS

EXAM. INITIALS		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB- CLASS	FILING DATE
	AA	4,160,152	07/03/79	Wightman et al.	219	438	12/04/78
	AB	4,256,108	03/17/81	Theeuwes	128	260	05/21/79
	AC	4,265,874	05/05/81	Bonsen et al.	424	15	04/25/80

FOREIGN PATENT DOCUMENTS

EXAM. INITIALS		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB- CLASS	TRANSLATIO N (YES/NO)
		NONE					


OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages)

AD	Adlercreutz and Mazur, "Phyto-oestrogens and Western Diseases," <i>Ann. Med.</i> , 29:95-120 (1997)
AE	Altschul et al., "Basic Local Alignment Search Tool," <i>J Mol. Biol.</i> , 215:403-410 (1990)
AF	Baes et al., "A New Orphan Member of the Nuclear Hormone Receptor Superfamily That Interacts with a Subset of Retinoic Acid Response Elements," <i>Molecular and Cellular Biology</i> , 14(3):1544-1552 (1994)
AG	Bahouth et al., "Immunological approaches for probing receptor structure and function," <i>TIPS Reviews</i> , 12:338-343 (1991)
AH	Bammel et al., "Divergent effects of different enzyme-inducing agents on endogenous and exogenous testosterone," 42:641-644 (1992)

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EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

FORM PTO-1449 U.S. Department of Commerce Patent and Trademark Office	Docket No. SALK2270-1	Serial No.: 09/227,718 RECEIVED
	Applicant(s): Ronald M. Evans AUG 30 2002	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT	Filing Date: January 8, 1999	Group Art Unit: 1643 TECH CENTER 1600/29

	AI	Barwick et al., "Trans-species Gene Transfer for Analysis of Glucocorticoid-Inducible Transcriptional Activation of Transiently Expressed Human CYP3A4 and Rabbit CYP3A6 in Primary Cultures of Adult Rat and Rabbit Hepatocytes," <i>Molecular Pharmacology</i> , 50:10-16 (1996)
	AJ	Beato et al., "Steroid Hormone Receptors: Many Actors in Search of a Plot," <i>Cell</i> , 83:851-857 (1995)
	AK	Beaune et al., "Isolation and sequence determination of a cDNA clone related to human cytochrome P-450 nifedipine oxidase," <i>Proc. Natl. Acad. Sci.</i> , 83:8064-8068 (1986)
	AL	Blumberg et al., "Novel retinoic acid receptor ligands in <i>Xenopus</i> embryos," <i>Proc. Natl. Acad. Sci.</i> , 93:4873-4878 (1996)
	AM	Blumberg et al., "BXR, an embryonic orphan nuclear receptor activated by a novel class of endogenous benzoate metabolites," <i>Genes & Development</i> , 12:1269-1277 (1998)
	AN	Burger et al., "Paradoxical transcriptional activation of rat liver cytochrome P-450 3A1 by dexamethasone and the antiglucocorticoid pregnenolone 16 α -carbonitrile: Analysis by transient transfection into primary monolayer cultures of adult rat hepatocytes," <i>Proc. Natl. Acad. Sci.(USA)</i> , 89:2145-2149 (1992)
	AO	Denison and Whitlock, "Xenobiotic-inducible Transcription of Cytochrome P450 Genes," <i>Journal of Biological Chemistry</i> , 270(31):18175-18178 (1995)
	AP	Devereux et al., "A comprehensive set of sequence analysis programs for the VAX," <i>Nucleic Acids Research</i> , 12:387-395 (1984)
	AQ	Edwards et al., "Changes in Cortisol Metabolism Following Rifampicin Therapy," <i>The Lancet</i> , 2:549-551 (1974)
	AR	Elshourbagy and Guzelian, "Separation, Purification, and Characterization of a Novel Form of Hepatic Cytochrome P-450 from Rats Treated with Pregnenolone-16 α -carbonitrile," <i>Journal of Biological Chemistry</i> , 255:1279-1285 (1980)
	AS	Enmark and Gustafsson, "Orphan Nuclear Receptors - The First Eight Years," <i>Mol. Endo.</i> , 10(11):1293-1307 (1996)

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AT	Evans, Ronald M., "The Steroid and Thyroid Hormone Receptor Superfamily," <i>Science</i> , 240:889-895 (1988)
AU	Fernandez-Salguero and Gonzalez, "The CYP2A gene subfamily: species differences, regulation, catalytic activities and role in chemical carcinogenesis," <i>Pharmacogenetics</i> , 5:S123-S128 (1995)
AV	Forman et al., "Unique Response Pathways Are Established by Allosteric Interactions among Nuclear Hormone Receptors," <i>Cell</i> , 81:541-550 (1995)
AW	Forman et al., "Hypolipidemic drugs, polyunsaturated fatty acids, and eicosanoids are ligands for peroxisome proliferator-activated receptors α and δ ," <i>Proc. Natl. Acad. Sci. USA</i> , 94:4312-4317 (1997)
AX	Gonzalez et al., "Complete cDNA and Protein Sequence of a Pregnenolone 16 α -Carbonitrile-induced Cytochrome P-450," <i>Journal of Biological Chemistry</i> , 260(12):7435-7441 (1985)
AY	Gonzalez et al., "Pregnenolone 16 α -Carbonitrile-Inducible P-450 Gene Family: Gene Conversion and Differential Regulation," <i>Molecular and Cellular Biology</i> , 6(8):2969-2976 (1986)
AZ	Gonzalez, Frank J., "Human cytochromes P450: problems and prospects," <i>TIPS Reviews</i> , 13:346-352 (1992)
BA	Gottlicher et al., "Fatty acids activate a chimera of the clofibrilic acid-activated receptor and the glucocorticoid receptor," <i>Proc. Natl. Acad. Sci. USA</i> , 89:4653-4657 (1992)
BB	Guengerich, F. Peter, "Metabolism of 17 α Ethynylestradiol in Humans", <i>Life Sciences</i> , 47:1981-1988 (1990)
BC	Hankinson, Oliver, "The Aryl Hydrocarbon Receptor Complex," <i>Annu. Rev. Pharmacol. Toxicol.</i> 35:307-340 (1995)
BD	Hardwick et al., "Cloning of DNA Complementary to Cytochrome P-450 Induced by Pregnenolone-16 α carbonitrile," <i>Journal of Biological Chemistry</i> , 258:10182-10186 (1983)

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	Applicant(s): Ronald M. Evans	
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BE	Henikoff and Henikoff, "Amino acid substitution matrices from protein blocks," <i>Proc. Natl. Acad. Sci. USA</i> , 89:10915-10919 (1992)
BF	Heuman et al., "Immunochemical Evidence for Induction of a Common Form of Hepatic Cytochrome P-450 in Rats Treated with Pregnenolone-16 α -carbonitrile or other Steroidal or Non-Steroidal Agents," <i>Molecular Pharmacology</i> , 21:753-760 (1982)
BG	Hollenberg et al., "Primary structure and expression of a functional human glucocorticoid receptor cDNA," <i>Nature</i> , 318(6047):635-641 (1985)
BH	Hollenberg et al., "Colocalization of DNA-Binding and Transcriptional Activation Functions in the Human Glucocorticoid Receptor," <i>Cell</i> , 49:39-46 (1987)
BI	Holtbecker et al., "The Nifedipine-Rifampin Interaction: Evidence for Induction of Gut Wall Metabolism," <i>Drug Metabolism and Disposition</i> , 23(10):1121-1123 (1996)
BJ	Jonat et al., "Antitumor Promotion and Antiinflammation: Down-Modulation of AP-1 (Fos/Jun) Activity by Glucocorticoid Hormone," <i>Cell</i> , 62:1189-1204 (1990)
BK	Juchau, M.R., "Substrate Specificities and Functions of the P450 Cytochromes," <i>Life Sciences</i> , 47:2385-2394 (1990)
BL	Kliwer et al., "Fatty acids and eicosanoids regulate gene expression through direct interactions with peroxisome proliferator-activated receptors α and γ ," <i>Proc. Natl. Acad. Sci. USA</i> , 94:4318-4323 (1997)
BM	Kliwer et al., "An Orphan Nuclear Receptor Activated by Pregnanes Defines a novel Steroid Signaling Pathway," <i>Cell</i> , 92:73-82 (1998)
BN	Kolars et al., "First-pass metabolism of cyclosporin by the gut," <i>Lancet</i> , 338:1488-1490 (1991)
BO	Kolars et al., "Identification of Rifampin-inducible P450III λ 4 (CYP3A4) in Human Small Bowel Enterocytes," <i>Journal of Clinical Investigation, Inc.</i> , 90:1871-1878 (1992)
BP	Kyriazopoulou et al., "Rifampicin-Induced Adrenal Crisis In Addisonian Patients Receiving Corticosteroid Replacement Therapy," <i>Journal of Clinical Endocrinology and Metabolism</i> , 59(6):1204-1206 (1984)

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FORM PTO-1449 U.S. Department of Commerce Patent and Trademark Office	Docket No. SALK2270-1	Serial No.: 09/227,118
	Applicant(s): Ronald M. Evans	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT	Filing Date: January 8, 1999	Group Art Unit: 1600/2901

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BQ	Kyriazopoulou and Vagenakis, "Abnormal Overnight Dexamethasone Suppression Test in Subjects Receiving Rifampicin Therapy," <i>Journal of Clinical Endocrinology and Metabolism</i> , 74(1):315-317 (1992)
BR	Ladias and Karathanasis, "Regulation of the Apolipoprotein AI Gene by ARP-1 a Novel Member of the Steroid Receptor Superfamily," <i>Science</i> , 251:561-565 (1991)
BS	Lee et al., "Time course of the changes in prednisolone pharmacokinetics after co-administration or discontinuation of rifampin," <i>Eur. Journal of Clinical Pharmacology</i> , 45:287-289 (1993)
BT	Li and Evans, "Ligation independent cloning irrespective of restriction site compatibility," <i>Nucleic Acids Research</i> , 25:4165-4166 (1997)
BU	Lonning et al., "Plasma Levels of Estradiol, Estrone, Estrone Sulfate and Sex Hormone Binding Globulin in Patients Receiving Rifampicin," <i>J. Steroid Biochem.</i> , 33(4A):631-635 (1989)
BV	Mangelsdorf et al., "The Nuclear Receptor Superfamily: The Second Decade," <i>Cell</i> , 83:835-839 (1995)
BW	Mangelsdorf and Evans, "The RXR Heterodimers and Orphan Receptors," <i>Cell</i> , 83:841-850 (1995)
BX	McAllister et al., "Rifampicin reduces effectiveness and bioavailability of prednisolone," <i>British Medical Journal</i> , 286:923-925 (1983)
BY	Miyata et al., "Transcriptional Elements Directing a Liver-Specific Expression of P450/6 β A (CYP3A2) Gene-Encoding Testosterone 6 β -Hydroxylase," <i>Archives of Biochemistry and Biophysics</i> , 318(1):71-79 (1995)
BZ	Molowa et al., "Complete cDNA sequence of a cytochrome P-450 inducible by glucocorticoids in human liver," <i>Proc. Natl. Acad. Sci. USA</i> , 83:5311-5315 (1986)
CA	Nebert, Daniel W., "P450 Genes: Structure, Evolution, and Regulation," <i>Ann. Rev. Biochem.</i> , 56:945-993 (1987)

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FORM PTO-1449 U.S. Department of Commerce Patent and Trademark Office	Docket No. SALK2270-1	Serial No.: 09/227,718
INFORMATION DISCLOSURE STATEMENT BY APPLICANT	Applicant(s): Ronald M. Evans	
	Filing Date: January 8, 1999	Group Art Unit: 1643



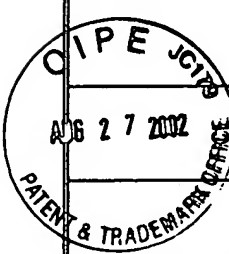
CB	Needleman and Wunsoh, "A General Method Applicable to the Search for Similarities in the Amino Acid Sequence of Two Proteins," <i>Journal of Molecular Biology</i> , 48:443-453 (1970)
CC	O'Malley and Conneely, "Orphan Receptors: In Search of a Unifying Hypothesis for Activation," <i>Molecular Endocrinology</i> , 6:1359-1361 (1992)
CD	Ogura and Evans, "A retinoic acid-triggered cascade of HOXB1 gene activation," <i>Proc. Natl. Acad. Sci. USA</i> , 92:387-391 (1995)
CE	Ohnhaus et al., "Urinary Excretion of 6 β -Hydroxycortisol and the Time Course Measurement of Enzyme Induction in Man," <i>Eur. J. Clin. Pharmacol.</i> , 36:39-46 (1989)
CF	Quattrochi et al., "A Novel cis-Acting Element in a Liver Cytochrome P450 3A Gene Confers Synergistic Induction by Glucocorticoids plus Antiglucocorticoids," <i>Journal of Biological Chemistry</i> , 270 (48):28917-28923 (1995)
CG	Russel and Wilson, "Steroid 5 α -Reductase: Two Genes/Two Enzymes," <i>Annu. Rev. Biochem.</i> , 63:25-61 (1994)
CH	Schuetz and Guzelian, "Induction of Cytochrome P-450 by Glucocorticoids in Rat Liver," <i>Journal of Biological Chemistry</i> , 259(3):1999-2006 (1984)
CI	Schuetz and Guzelian, "Induction of Cytochrome P-450 by Glucocorticoids in Rat Liver," <i>Journal of Biological Chemistry</i> , 259(3):2007-2012 (1984)
CJ	Schule et al., "Functional Antagonism between Oncoprotein c-Jun and the Glucocorticoid Receptor," <i>Cell</i> , 62:1217-1226 (1990)
CK	Selye, H., "Hormones and Resistance," <i>Journal of Pharmaceutical Sciences</i> , 60(1):1-28 (1971)
CL	Sucov et al., "Characterization of an autoregulated response element in the mouse retinoic acid receptor type β gene," <i>Proc. Natl. Acad. Sci. USA</i> , 87:5392-5396 (1990)
CM	Staden, Rodger, "The current status and portability of our sequence banding software," <i>Nucleic Acids Research</i> , 14(1):217-231 (1986)

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FORM PTO-1449 U.S. Department of Commerce Patent and Trademark Office	Docket No. SALK2270-1	Serial No.: 09/227,718
	Applicant(s): Ronald M. Evans	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT	Filing Date: January 8, 1999	Group Art Unit: 1643

	CN	Terzolo et al., "Misdiagnosis of Cushing's Syndrome in a Patient Receiving Rifampicin Therapy for Tuberculosis," <i>Horm. Metab. Res.</i> , 27:148-150 (1995)
	CO	Umesono et al., "Direct Repeats as Selective Response Elements for the Thyroid Hormone, Retinoic Acid, and Vitamin D ₃ Receptors," <i>Cell</i> , 65:1255-1266 (1991)
	CP	Watkins et al., "Erythromycin Breath Test as an Assay of Glucocorticoid-inducible Liver Cytochromes P-450," <i>J. Clin. Invest.</i> , 83:688-697 (1989)
	CQ	Wietholtz et al., "Stimulation of bile acid 6 α -hydroxylation by rifampin," <i>Journal of Hepatology</i> , 24:713-718 (1996)
	CR	Willy et al., "LXR, a nuclear receptor that defines a distinct retinoid response pathway," <i>Genes & Development</i> , 9:1033-1045 (1995)
	CS	Wurtz et al., "A canonical structure for the ligand-binding domain of nuclear receptors," <i>Nature Structural Biology</i> , 3:87-94 (1996)
	CT	Yang-Yen et al., "Transcriptional Interference between c-Jun and the Glucocorticoid Receptor: Mutual Inhibition of DNA Binding Due to Direct Protein-Protein Interaction," <i>Cell</i> , 62:1205-1215 (1990)
	CU	Zawawi et al., "The Effects of Therapy with Rifampicin and Isoniazid on Basic Investigations for Cushing's Syndrome," <i>Ir. j. Med. Sci.</i> , 165:300-302 (1996)

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Applicant: Evans et al. Art Unit: 1632
Application No.: 09/458,366 Examiner J. Woitach
Filed: December 9, 1999
Title: NOVEL STEROID-ACTIVATED NUCLEAR RECEPTORS AND USES
THEREFOR

CERTIFICATION UNDER 37 CFR §1.18	
I hereby certify that the documents referred to as enclosed herein are being hand-delivered on <u>11/29/00</u> to: Commissioner for Patents, Washington, D.C. 20231.	
<u>Stephen E. Reiter,</u>	Reg. No.: <u>31,192</u>
Name of Person Hand-Delivering Paper	
<u>[Signature]</u>	<u>11/29/00</u>
Signature	Date

Box IDS
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Washington, D.C. 20231

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

Sir:

In accordance with 37 C.F.R. § 1.97(c), enclosed are references relating to the above-identified application. For the convenience of the Examiner, these references are listed on the attached Form PTO-1449 and a copy of each is enclosed herewith.

It is respectfully requested that these references be considered in the examination of this application and that such consideration be made of written record in the application file.

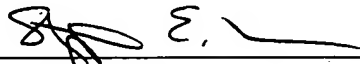
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Applicant: Evans et al.
Application No.: 09/458,366
Filed: December 9, 1999
Page 2

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Respectfully submitted,

Dated: 11/29/00



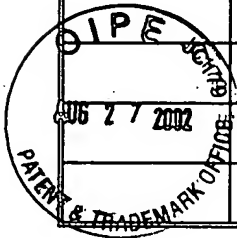
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FORM PTO-1449 U.S. Department of Commerce Patent and Trademark Office	Docket No. (Optional) SALK2270-2	Serial No.: 09/458,366
	Applicant(s): EVANS ET AL	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT	Filing Date: DECEMBER 9, 1999	Group Art Unit: 1632

U.S. PATENT DOCUMENTS

EXAM. INITIALS		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB- CLASS	FILING DATE



FOREIGN PATENT DOCUMENTS

EXAM. INITIALS		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB- CLASS	TRANSLATION (YES/NO)
		99/19354	22APR99	WO	6		
		99/61622	2DEC99	WO	6		
		99/489915	22SEP99	WO	6		

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